REMARKS

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

Status of the Claims

Claims 1-4 and 6-9 are currently pending and stand ready for further action on the merits for the above-identified application. Claim 1 was amended without prejudice or disclaimer. No new matter has been added by way of amendment. Support for claim 1 can be found on page 3, lines 7-16, page 4, lines 7-21, and page 10, line 25 to page 12, line 7 of the present specification. Thus, no new matter has been added.

Based upon the above considerations, entry of the present Amendment is respectfully requested.

Issues Regarding Information Disclosure Statement (IDS)

The Examiner states that the IDS filed January 17, 2008 fails to comply with the provisions of 37 C.F.R. § 1.97 and MPEP § 609 because there is no translation of JP- 09-216817 and JP-09-511257-A in full or abstract form.

For the IDS mentioned above, JP- 09-216817-A was supplied to the Examiner with an English translated abstract. For the convenience of the Examiner, Applicants have submitted an additional English translated abstract as well as the detailed description.

With regards to JP-09-511257-A, for the convenience of the Examiner, Applicants herein enclose U.S. Patent No. 5,626,875 which is an English equivalent to JP-09-511257-A.

Applicants believe the submission of the enclosed IDS resolves the above issue. Applicants respectfully request reconsideration of the above cited references.

Issues Under 35 U.S.C. § 102(b), Anticipation

The Examiner has rejections under 35 U.S.C. § 102(b) as follows:

Claim 6 stands rejected under 35 U.S.C. § 102(b) as anticipated by Depui *et al.*, WO 97/25066 (hereinafter "Depui").

The Examiner suggests that all the critical elements are taught by Depui, including dosage forms comprising proton pump inhibitors, bases (antacid agents), alginates, thickeners, polymers (including enteric polymers) and other pharmaceutical excipients to form multilayered tablets, sachets and multiple unit tableted dosage forms. The Examiner also asserts that this also includes the multiple unit dosage form which is to be dispersed in liquid and can be given to patients with swallowing disorders or to pediatric patients. The Examiner alleges that since all the critical elements of the granules are taught within Depui, the viscosity of the granules would be inherent to the composition.

Claim 6 stands rejected under 35 U.S.C. § 102(b) as anticipated by Ukai *et al.*, U.S. Patent Application No. 2002/0039597 (hereinafter "Ukai").

As in the above rejection, the Examiner suggests that Ukai teach all the critical elements of the present invention. This includes specific benzimiadzole type compounds and their alkali salts (which are all proton pump inhibitors), bases, thickeners, polymers (including enteric polymers), and other pharmaceutical excipients that are formed into tablets soluble or rapidly degradable (dispersible) in water or in gastric acid. The Examiner further suggests that proton

pump inhibitors are in granular form, individually enterically coated with a polymer (including hydroxypropyl methylcellulose), combined with bases, crospovidone, granules not containing the proton inhibitors ("placebo"), and other excipients to be compressed into a tablet. The Examiner also asserts that the formulated core material is made, granulated, dried, and screened through a 24-mesh screen, producing particle sizes of about 841 micron or less and that Tables 6-13 and examples 28-29 of Ukai fulfill the claims. The Examiner also alleges here that since all the critical elements of the granules are taught within Ukai the viscosity of the granules would be inherent to the composition.

Claims 1-5 and 7-8 stand rejected under 35 U.S.C. § 102(b) as anticipated by Depui. The Examiner asserts that Depui anticipates the present invention since all the critical elements are taught in each reference (as discussed above for the new rejections).

Claims 1-5 and 7-8 stand rejected under 35 U.S.C. § 102(b) as anticipated by Ukai. As above, the Examiner asserts that Ukai individually anticipates the present invention since all the critical elements are taught in each reference.

Applicants respectfully traverse the above anticipatory rejections.

Legal Standard for Determining Anticipation

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art." *Brown v. 3M*, 265 F.3d 1349, 1351, 60 USPQ2d 1375, 1376 (Fed. Cir.

2001) "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Distinctions Over the Cited Art

Rejection of claims based on Depui

Applicants have amended claim 1, without prejudice or disclaimer to further clarify the invention. Based on a full review of the presently amended claims, Applicants believe that there are distinctions between the present invention and the cited references Depui and Ukai.

With regards to Depui, as described in page 11, line 16 of the Office Action dated April 21, 2008, the Examiner regards the granules with an alginate/antacid as a placebo-without the active proton pump inhibitor. Applicants respectfully disagree with the Examiner's assertion.

Applicants note to the Examiner that Depui discloses "The present preparations comprise a combination of different gastric acid-suppressing agents, such as an acid susceptible proton pump inhibitor, and antacid agent(s) and/or alginate..." in page 1, line 7 to 9 and "Antacid agents and alginates may be used alone in the treatment of heartburn." in page 2, line 6. By this description, this means that the reference discloses the granules as a medicament. Therefore there is no disclosure relating to placebo granules in Depui. Since claim 6 depends from claim 1, the rejections cited to Depui have been overcome.

In light of the above, Applicants further believe that the Depui reference as a 35 U.S.C. § 102(b) anticipation reference is improper. There is no anticipation or inherency because Depui

uses medicaments instead of the placebo granules as extenders for the active granules of the present invention. Thus, because of the lack of disclosure of all features as instantly claimed, the rejections in view of Depui are overcome.

Rejection of claims based on Ukai

With regards to Ukai, the active granules of the present invention contain seeds having a coating that contains the pharmaceutically active substance and wherein the active granules have an average particle diameter of 2 mm or less, which are not disclosed in Ukai. The present invention has seeds where the active granules include the seeds, placebo granules and a thickening agent. Ukai does not disclose this. Ukai fails to show a structure obtained by coating seeds with a pharmaceutically active substance. This is exemplified in the referenced tables 6-13 (examples 4-9) and examples 28-29. The table and examples referenced by the Examiner do not teach this element. Since the amended claim 1 of the instant application includes "seeds having a coating that contains the pharmaceutically active substance" the rejection is overcome.

Since claim 6 depends from claim 1, the rejection cited to Ukai for claim 6 has also been overcome.

In light of the above, Applicants further believe that the Ukai reference as a 35 U.S.C. § 102(b) anticipation reference is improper. There is no anticipation or inherency because Ukai does not disclose the active granules of the present invention, which contain seeds having a coating that contains the pharmaceutically active substance. Thus, because of the lack of disclosure of all features as instantly claimed, the rejections in view of Ukai are overcome.

In light of the above, the cited rejections have been overcome. Applicants respectfully request reconsideration and withdrawal of the above cited rejections.

Issues Under 35 U.S.C. § 103(a), Obviousness

The Examiner has recited rejections under 35 U.S.C. §103(a) as follows:

Claim 9 stands rejected under 35 U.S.C. § 103(a) as obvious over Depui, as applied to claims 1-4 and 6-8, in view of Pharmaceutical Dosage Forms: Tablets(Volume 1, second edition; hereinafter "PDFT").

Claim 9 stands rejected under 35 U.S.C. § 103(a) as obvious over Ukai, as applied to claims 1-4 and 6-8, in view of PDFT and Samejima *et al.* U.S. Patent No. 5,068,112 (hereinafter "Samejima").

With regards to Depui, the Examiner asserts that the limitations have been met as discussed above and additionally states that Depui teaches the inclusion of layer substances for antacid formulations for improved properties such as pH-buffering with components such as citric acid and talc. The Examiner states that Depui does not expressly teach the incorporation of light anhydrous silicic acid (silicone dioxide). The Examiner does assert, however, that PDFT teaches the benefits of anti-adherents and glidants in formulations. Also, the Examiner suggests that PDFT teaches that talc, Cab-O-Sil, and Syloid are analogous materials for both anti-adherent and glidant properties and teaches that silica has greater efficiency as a glidant than magnesium stearate or purified talc.

The Examiner further asserts that it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute light anhydrous silicic acid for talc or magnesium stearate, as suggested by PDFT and produce the instant invention since it would have been obvious to substitute one material for another depending on the desired flow

property and adhesion for the product.

With regards to Ukai *et al.* the Examiner Asserts that the limitations have been met as discussed above. The Examiner states Ukai does not expressly teach the incorporation of anhydrous silicic acid (silicon dioxide) or citric acid. The Examiner does suggest, however that PDFT teaches the benefits of anti-adherents and glidants in formulations and teaches that talc, Cab-O-Sil, and Syloid are analogous materials for both anti-adherent and glidant properties and teaches that silica has greater efficiency as a glidant than magnesium stearate or purified talc. Additionally, the Examiner asserts that Samejima *et al.* teaches that known buffers for pharmaceutical preparations such as granules are organic acids such as fumaric acid, succinic acid, citric acid, and malic acid.

Applicants respectfully traverse the above mentioned rejections.

Legal Standard for Determining Prima Facie Obviousness

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

"There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *In re Rouffet,* 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998) (The combination of the references taught every element of the claimed invention, however without a motivation to combine, a rejection based on a *prima facie* case of obvious was held improper.).

"In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." *In re Linter*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. "The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." *In re Kotzab,* 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). See also *In re Lee,* 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (discussing the importance of relying on objective evidence and making specific factual findings with respect to the motivation to combine references); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

The Supreme Court of the United States has recently held that the teaching, suggestion, motivation test is a valid test for obviousness, but one which cannot be too rigidly applied. See *KSR Int'l Co. v Teleflex Inc.*, 127 SCt 1727, 82 USPQ2d 1385 (U.S. 2007). The Supreme Court in *KSR Int'l Co. v. Teleflex, Inc., ibid.,* reaffirmed the Graham factors in the determination of obviousness under 35 U.S.C. § 103(a). The four factual inquiries under Graham are:

(a) determining the scope and contents of the prior art;

(b) ascertaining the differences between the prior art and the claims in issue;

(c) resolving the level of ordinary skill in the pertinent art; and

(d) evaluating evidence of secondary consideration.

Graham v. John Deere, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (U.S. 1966).

The Court in *KSR Int'l Co. v. Teleflex, Inc., supra.,* did not totally reject the use of "teaching, suggestion, or motivation" as a factor in the obviousness analysis. Rather, the Court recognized that a showing of "teaching, suggestion, or motivation" to combine the prior art to meet the claimed subject matter could provide a helpful insight in determining whether the claimed subject matter is obvious under 35 U.S.C. § 103(a).

Even so, the Court in *KSR Int'l Co. v. Teleflex, Inc., ibid.,* rejected a rigid application of the "teaching, suggestion, or motivation" (TSM) test, which required a showing of some teaching, suggestion, or motivation in the prior art that would lead one of ordinary skill in the art to combine the prior art elements in the manner claimed in the application or patent before holding the claimed subject matter to be obvious.

Further, the Examiner bears the initial burden of presenting a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

"[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336, quoted with approval in *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007).

Distinctions Over the Cited Art

The arguments from the previous anticipatory rejections are herein incorporated by reference. Based on a full review of the presently amended claims, and the arguments above, Applicants believe that there are distinctions between the present invention and the cited primary references Depui and Ukai. Therefore, the addition of PDFT with Depui or the addition of PDFT and Samejima to Ukai fail to resolve the deficiencies of the cited primary references.

In light of the presently amended claims and the arguments above, it is noted that neither of the cited primary prior art references (*i.e.*, Depui nor Ukai) provide any teaching or disclosure that would allow one of ordinary skill in the art to arrive at the instant invention as claimed. More particularly, one of ordinary skill in the art, upon considering the disclosures of each of Depui and Ukai, would find no reason or rationale in the cited art to arrive at the instant invention as claimed. As such, it follows that neither of the cited art references' disclosures can serve as a proper basis for rejecting any of instantly pending claims 1-4 and 6-9 under the provisions of 35 U.S.C. § 103(a). Any contentions of the USPTO to the contrary must be reconsidered at present.

In light of the cited case law above, the lack of disclosure of all features as instantly claimed, the rejection in view of Depui with PDFT and the rejection in view of Ukai, PDFT and

Samejima are overcome and/or rendered moot.

In view of the above remarks, Applicants believe the pending application is in condition for allowance.

CONCLUSION

In view of the above comments, Applicants respectfully submit that instant claims 1-4, and 6-9 are allowed and patentable under the provisions of title 35 of the United States Code. A notice to such effect is earnestly solicited at present.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Paul D. Pyla, Reg. No. 59,228, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: July 21, 2008

Respectfully submitted,

By _____

John W. Bailey
Registration No.: 32,881
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road
Suite 100 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(703) 205-8000
Attorney for Applicants